

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**UNITED STATES OF AMERICA,
STATES OF CALIFORNIA,
COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA,
HAWAII, ILLINOIS, INDIANA, IOWA,
LOUISIANA, MICHIGAN,
MINNESOTA, MONTANA, NEVADA,
NEW JERSEY, NEW MEXICO, NEW
YORK, NORTH CAROLINA,
OKLAHOMA, RHODE ISLAND,
TENNESSEE, TEXAS, VERMONT,
AND WASHINGTON; THE
COMMONWEALTHS OF
MASSACHUSETTS AND VIRGINIA;
AND THE DISTRICT OF COLUMBIA,**

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

v.

**JANSSEN BIOTECH, INC., JANSSEN
ONCOLOGY, INC., JANSSEN
RESEARCH & DEVELOPMENT, LLC,
and JOHNSON & JOHNSON,**

Defendants.

Civ. No. 19-12107 (KM) (ESK)

OPINION & ORDER

KEVIN MCNULTY, U.S.D.J.:

On June 20, 2019, Plaintiff Zachary Silbersher, as relator, filed the operative Second Amended Complaint alleging claims for violations of the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, and numerous state laws against Defendants Johnson & Johnson (“J&J”) and subsidiaries Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC, in connection with their acquisition of a patent covering the pharmaceutical drug

Zytiga. (DE 63.)¹ On December 17, 2021, I denied Defendants’ motion to dismiss as to J&J and its subsidiaries.² (DE 180) Defendants now move, pursuant to 28 U.S.C. § 1292(b), to certify an interlocutory appeal on the question of whether information disclosed in inter partes review (“IPR”) proceedings or on the Patent and Trade Office’s (“PTO”) PAIR database triggers the FCA’s public disclosure bar.³ (Defs. Mot. at 1-2, 7.) Additionally, Defendants move for a stay pending appeal. (*Id.* at 1, 19.) For the following reasons, the motion is **DENIED**.

I. BACKGROUND

I assume familiarity with the factual background and procedural history of the instant dispute as set forth in my prior opinion denying, in part, Defendants’ motion to dismiss. (*See* DE 179 at 2-9.) In that opinion, I rejected Defendants’ argument that the substance of Plaintiff’s allegations was publicly disclosed in one of the three enumerated channels triggering the FCA’s public disclosure bar.⁴ Specifically, I concluded that IPR proceedings did not

¹ Certain citations to the record are abbreviated as follows:

DE refers to the docket entry numbers in this case.

Defs. Mot. refers to Defendants’ Memorandum in Support of Defendants’ Motion to Certify Interlocutory Appeal and for a Stay (DE 182-1).

Op. refers to Plaintiff’s Brief in Opposition to Defendants’ Motion (DE 185).

² However, I granted Defendant’s motion with reference to Defendant BTG International, Ltd. (“BTG”), finding that Plaintiff had failed to plead detail regarding BTG’s conduct “at the level of specificity contemplated by Rule 9(b).” (DE 179 at 25.)

³ As noted in my prior opinion, the Patent Application Information Retrieval, or “PAIR,” system is an online database where the PTO is required to publish patent applications “promptly” once 18 months have elapsed since “the earliest filing date for which a benefit is sought.” (DE 179 at 15, n.14 (citing 35 U.S.C. § 122; 37 C.F.R. §1.211)).

⁴ The public disclosure bar requires a court to dismiss an FCA action or claim “if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed” in one of three enumerated sources: (i) “a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party” (“channel (i)”); (ii) “a congressional, Government Accountability Office, or other Federal

constitute a federal hearing under either channel (i) or (ii), while documents published on the PAIR system did not constitute a federal report under channel (ii). (DE 179 at 13-16.) To find otherwise, I reasoned, would ignore the evident intent behind Congress's 2010 amendments to the FCA which limited channel (i) to federal hearings in which the Government is a party. (DE 179 at 14-16.)

Defendants now urge that I certify for interlocutory appeal the questions of whether IPR proceedings qualify as "federal hearings" or whether documents on the PAIR system qualify as "federal reports" within the meaning of channel (ii) of the FCA's public disclosure bar. (Defs. Mot. at 7.)

II. DISCUSSION AND ANALYSIS

Generally, a litigant may appeal only final decisions of federal district courts. *Def. Distrib. v. Att'y Gen. of N.J.*, 972 F.3d 193, 198 (3d Cir. 2020). Interlocutory orders, like a partial dismissal, merge with the final judgment, and so an appeal encompasses review of such orders. *See Verma v. 3001 Castor, Inc.*, 937 F.3d 221, 228 (3d Cir. 2019) (stating general merger rule). The final judgment rule, however, is "subject to limited exceptions." *Def. Distrib.*, 972 F.3d at 198.

One such exception is for certified questions. A non-final order may be certified for appeal if the court determines that it (1) involves a "controlling question of law," (2) for which there is "substantial ground for difference of opinion," and (3) which may "materially advance the ultimate termination of the litigation" if appealed immediately. 28 U.S.C. § 1292(b). A "controlling question of law" is one which, if answered erroneously, would result in reversal on appeal, or which is "serious to the conduct of the litigation, either practically or legally." *Hall v. Wyeth, Inc.*, 2010 WL 4925258 at *1 (D.N.J. Dec. 2, 2010) (quoting *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974) (en banc)); *see also Ensey v. Gov't Employers Ins. Co.*, No. CV 12-7669 (JEI/KMW), 2014 WL 12613400, at *2 (D.N.J. Aug. 18, 2014). A "substantial ground for

report, hearing, audit, or investigation" ("channel (ii)"); or (iii) "news media" ("channel (iii)"). 31 U.S.C. § 3730(e)(4)(A)(i)-(iii).

difference of opinion” exists where “courts that have examined an issue reach ‘conflicting and contradictory opinions . . . upon the particular question of law.’” *Ensey*, 2014 WL 12613400 at *2 (quoting *Kolbeck v. General Motors Corp.*, 702 F. Supp. 532, 542 (E.D. Pa. 1988)); *see also* *Cuttic v. Crozer–Chester Med. Ctr.*, 806 F. Supp. 2d 796, 804–05 (E.D. Pa. 2011) (“[S]ubstantial grounds for difference of opinion exist where there is general doubt or conflicting precedent as to the correct legal standard.”). Finally, certification may materially advance a lawsuit’s ultimate termination where “the moving party shows that an immediate appeal would (1) eliminate the need for trial, (2) reduce the extent or cost of discovery, or (3) simplify the trial by eliminating complex issues.” *Children First Found., Inc. v. Legreide*, Civ. No. 04-2137, 2005 WL 3088334, at *10 (D.N.J. Nov. 17, 2005).

Certification is, however, discretionary, and I may decline certification of a question for immediate appeal even if the three criteria are met. *Ensey*, 2014 WL 12613400 at *2 (citing *Bachowski v. Usery*, 545 F.2d 363, 368 (3d Cir. 1976); *ADP, LLC v. Ultimate Software Grp., Inc.*, Civ. No. 16-8664, 2018 WL 1838003, at *3 (D.N.J. Apr. 17, 2018). Moreover, the Third Circuit has long disfavored piecemeal appeals and departing from the final judgment rule. *See Def. Distrib.*, 972 F.3d at 198; *Camesi v. Univ. of Pittsburgh Med. Ctr.*, 729 F.3d 239, 244 (3d Cir. 2013); *see also* *Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 479 n.7 (1975) (“[I]n deciding the question of finality the most important competing considerations are ‘the inconvenience and costs of piecemeal review on the one hand and the danger of denying justice by delay on the other.’” (quoting *Gillespie v. United States Steel Corp.*, 379 U.S. 148, 152-53 (1964))).

Turning to the case before me, I find as to the first element that Defendants have successfully shown that the issues for which they seek certification involve “controlling question[s] of law.” The question of whether information disclosed in IPR proceedings or on the PTO’s PAIR system triggers channel (ii) of the FCA’s public disclosure bar is unquestionably of serious practical and legal importance to Plaintiff’s case; if this information is barred

on public disclosure grounds, Plaintiff's claims will lose the bulk of their supporting allegations. Though Plaintiff urges that he may nonetheless fall back on the argument that he is an "original source," (Op. at 5), the scope of the public disclosure bar remains of obvious importance to the conduct of the instant litigation. *See Katz*, 496 F.2d at 755.

However, despite the importance of the questions proposed for certification, Defendants have failed to show that these questions are ones on which there is "substantial ground for difference of opinion." Indeed, there is no indication that the status of information disclosed in IPR proceedings or on the PAIR system is a cause of "general doubt or conflicting precedent." *See Cuttic*, 806 F. Supp. 2d at 804–05. Rather, Defendants have only cited the disagreement between two district courts from California's Northern District: *Silbersher v. Valeant Pharms. Int'l, Inc.*, finding that information disclosed in IPR proceedings qualified as a public disclosure in a federal hearing under channel (ii), 445 F. Supp. 3d 393, 405-06 (N.D. Cal. 2020), and *Silbersher v. Allergan Inc.*, finding that such information did not qualify as a public disclosure and noting that *Valeant's* interpretation of federal hearing "appears to be in direct conflict with what Congress intended when it amended the public disclosure bar in 2010," 506 F. Supp. 3d 772, 807-09 (N.D. Cal. 2020). This disagreement alone does not, of course, demonstrate conflicting precedent within the Third Circuit and Defendants have offered no further authority to suggest one exists. *See, e.g., Cosimano v. Twp. of Union*, 2017 WL 4790381 at *2 (D.N.J. Oct. 23, 2017) ("the substantial ground for difference of opinion must be within the Third Circuit"). Moreover, most courts in this District have found that an issue of first impression does not provide substantial grounds for difference of opinion because, by definition, no other court has disagreed. *See e.g., id.; Inserra Supermarkets, Inc. v. Stop & Shop Supermarket Co., LLC*, No. 16-CV-01697, 2017 WL 3189029, at *3 (D.N.J. July 27, 2017). Thus, on balance, Defendants have failed to show a "substantial ground for difference of opinion" warranting the certification of their proposed questions.

While the lack of a substantial ground for difference of opinion is enough, standing alone, to be fatal to Defendants' motion, I also note that it remains speculative whether an immediate appeal would "materially advance the ultimate termination of the litigation." Indeed, even assuming Defendants prevailed upon appeal, such a victory would not assuredly eliminate the need for trial, simplify trial issues, or reduce discovery's extent or cost if Plaintiff pursues his alternative argument that he qualifies as an original source. *See Children First Found.*, Civ. No. 04-2137, 2005 WL 3088334, at *10. On the other hand, if Defendants were allowed to appeal and lost, "the danger of denying justice by delay" would grow only more acute. *See Cox Broad. Corp.*, 420 U.S. at 479 n.7. As such, and with our precedent's well-established policy against piecemeal appeals and departure from the final judgment rule in mind, I will not allow Defendants to appeal at this stage of litigation. *See Def. Distrib.*, 972 F.3d at 198; *Camesi*, 729 F.3d at 244.

III. ORDER

IT IS THEREFORE, this 26th day of January 2022,

ORDERED that Defendants' motion for certification and stay pending appeal (DE 182) is **DENIED**.

/s/

Hon. Kevin McNulty
United States District Judge